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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/068,935	11/23/1998	DAVID PASCUAL	47714-5004	2851

7590

04/10/2002

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EXAMINER

GAMBEL, PHILLIP

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 04/10/2002

20

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. <u>068935</u> <u>09/08/08</u>	Applicant(s) <u>PASCUAL</u>	
	Examiner <u>GAMBER</u>	Art Unit <u>1644</u>	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on .

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 55-111 is/are pending in the application.

4a) Of the above claim(s) is/are withdrawn from consideration. 60, 61, 65, 66, 69-71, 73-75, 77-79

5) ☐ Claim(s) is/are allowed. 81, 84, 84, 85, 88, 91-97, 107, 108

6) ☒ Claim(s) is/are rejected. 55-59, 61-64, 67, 68, 72 110, 111

7) ☐ Claim(s) is/are objected to. 76, 80, 83, 86, 87, 89, 90, 98-106, 109

8) ☐ Claim(s) are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.

15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). <u> </u>
2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u> </u>	6) <input type="checkbox"/> Other: <u> </u>

DETAILED ACTION

1. Applicant's election of an attachment molecules comprising proteins and glycoproteins, endothelial cells, mannose, selectin or integrin, ICAM-1 and Candida in Paper No. 17 has been acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

According to applicant, claims 55-90 and 95-111 correspond to the elected Group I.
See page 16 of applicant's election, filed 5/17/01 (Paper No. 17).

However, claims 95-97 read on kits comprising antibodies and not pathogen adhesins. Antibodies and pathogen adhesins differ in structure, physicochemical properties and modes of actions and are considered distinct.

It appears that claims 55-59, 62-64, 67, 68, 72, 76, 80, 83, 86, 87, 89, 90, 98-106 and 109 read on the elected invention an attachment molecules comprising proteins and glycoproteins, endothelial cells, mannose, selectin or integrin, ICAM-1 and Candida .

If applicant disagrees, applicant should point out the claims that do read on the elected invention.

Claims 60, 61, 65, 66, 69-71, 73-75, 77-79, 81, 82, 84, 85, 88, 91-97, 107, 108, 110 and 111 are withdrawn from consideration as being directed to a non-elected invention/species. See 37 C.F.R. § 1.142(b) and M.P.E.P. § 821.03.

Claims 1-54 have been canceled previously.

It has been noted that vaccines appear to comprise a single active or critical element, namely the pathogen adhesin molecule.

Therefore, it appears that claims appear to be drawn to pathogens set forth in claims 73-83, irregardless of the adhesion molecule on a host cell or extracellular matrix

Given that this may not have been applicant's intent, a Restriction was set forth in Paper No. 18, mailed 11/29/01, for the following reason.

Given the interpretation that the claims read on the active or critical element of the pathogens set forth in claims 73-83, these pathogens and immunogenic fragments thereof, differ in structure and modes of action to such an extent and require non-coextensive searches to such an extent that they are considered separately patentable. For example, the vaccines encompass a broad, diverse and structural distinct spectrum of pathogens.

In the Interview Summary on 11/29/01 (Paper No. 19), the examiner indicated that a first action on the merits would be forthcoming based upon the election set forth in Paper No. 17.

The examiner apologizes for any inconvenience to applicant in this matter.

Again, it is noted that the claims appear to simply read on well known vaccine formulations of a broad spectrum of pathogens at the time the invention was made.

2. Applicant's submission of a Search Report on the IDS is acknowledged, however this citation has been crossed out as it is not appropriate for an IDS.

3. Drawings have been submitted which fail to comply with 37 CFR 1.84.
Please see the enclosed form PTO-948.

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

A. Correction of Informalities -- 37 CFR 1.85

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings MUST be filed within the THREE MONTH shortened statutory period set for reply in the "Notice of Allowability." Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136 for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

B. Corrections other than Informalities Noted by Draftsperson on form PTO-948.

All changes to the drawings, other than informalities noted by the Draftsperson, MUST be made in the same manner as above except that, normally, a highlighted (preferably red-ink) sketch of the changes to be incorporated into the new drawings MUST be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

Timing of Corrections

Applicant is required to submit acceptable corrected drawings within the time period set in the Office action. See 37 CFR 1.185(a). Failure to take corrective action within the set (or extended) period will result in ABANDONMENT of the application.

4. If applicant desires priority under 35 U.S.C. 120 based upon a previously filed copending application, specific reference to the earlier filed application must be made in the instant application. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No. _____" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

Applicant should amend the first line of the specification to update the status of the priority documents.

5. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. Applicant should restrict the title to the claimed invention.

6. This application does not contain an Abstract of the Disclosure as required by 37 CFR 1.72(b). An Abstract on a separate sheet is required.

7. The application is required to be reviewed and all spelling, TRADEMARKS, and like errors corrected.

Trademarks should be capitalized or accompanied by the TM or ® symbol wherever they appear and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the trademarks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Appropriate corrections are required

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

9. Claims 55-59, 62-64, 67, 68, 72, 76, 80, 83, 86, 87, 89, 90, 98-106 and 109 are rejected under 35 U.S.C. § 102(e) as being anticipated by Cutler et al. (U.S. Patent No. 5,578,309) (see previous 892, mailed 10/9/01 in Paper No. 18) alone as well as acknowledged by applicant's disclosure on page 2, paragraphs 1-2 of the specification. .

Cutler et al. teach *Candida albicans* vaccines (see entire document, including Background of the Invention, Summary of the Invention, Detailed Description of the Invention and Claims. Therefore, it appears that Cutler et al. teach *Candida albicans* vaccine that anticipate the claimed and elected invention. Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. The claimed functional limitations encompassing the elected invention of attachment molecules comprising proteins and glycoproteins, endothelial cells, mannose, selectin or integrin, ICAM-1 and *Candida* as well as the claimed characteristics (e.g specificity, shear conditions, would be inherent properties of the referenced *Candida albicans* vaccines.

Products of identical chemical composition can not have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01.

Also, see Mehl/Biophile International Corp. V. Milgraum, 52 USPQ2d 1303 (Fed. Cir. 1999) and Atlas Powder Co. V. IRECO, 51 USPQ2d 1943 (Fed. Cir. 1999); For example in Atlas Powder Co. V. IRECO, 51 USPQ2d 1943 (Fed. Cir. 1999); the following was noted. "Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art... However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer. " The Court further held that "this same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art".

Page 2, paragraphs 1-2 of the specification acknowledges that the disclosure of Cutler et al. In USSN 08/483,558, now U.S. Patent No. 5,578,309 discloses vaccines for the treatment of *Candida albicans* comprising adhesion molecules but "did not recognize that pathogens and infectious agents use the host cell's own machinery to mimic the host and enter cell and tissue with relative ease".

Again, the claimed functional limitations would be inherent properties of the referenced *Candida* vaccines.

10. No claim allowed.

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11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (703) 308-3997. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.



Phillip Gambel, PhD.
Primary Examiner
Technology Center 1600
April 9, 2002